

**Testimony of James Binns
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U.S. House of Representatives Committee on Government Reform
Subcommittee on National Security, Veterans Affairs, and International Relations
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Mr. Chairman, Members of the Committee, for nearly four years I have had the privilege of chairing the Research Advisory Committee on Gulf War Veterans Illnesses. In the same 1998 law that established the Research Advisory Committee, Congress directed the Department of Veterans Affairs to contract with the National Academy of Sciences. The Academy's Institute of Medicine, the IOM, was to review the scientific literature regarding substances to which troops were exposed in the Gulf to determine if these substances are associated with an increased risk of illness. These reports were to be used by the Secretary of Veterans Affairs in determining whether such an illness should be presumed service-connected and thus trigger veterans benefits.

I regret to inform you that for seven years VA and IOM staff have subverted the will of Congress and misled the Secretary of Veterans Affairs regarding scientific research governing veterans benefits.

Staff shaped the methodology of the reports, so that scientists who served on IOM committees were not permitted to consider an essential category of research mandated by law.

The law provided that:

“The National Academy of Sciences shall determine ...

(A) whether a statistical association exists between exposure to the agent ... and the illness ...

(B) the increased risk of the illness among human or animal populations exposed to the agent ... and

(C) whether a plausible biological mechanism or other evidence of a causal relationship exists ...”

38 USC Sec. 1117, note Sec. 1603(e) [emphasis added] [Tab 1]

The statute went on to provide that the Secretary of Veterans Affairs should consider animal studies in determining whether a presumption of service connection is warranted. He was to consider “the exposure in humans or animals” to an agent and “the occurrence of a diagnosed or undiagnosed illness in humans or animals.”

38 USC Sec. 1118 (b)(1)(B) [emphasis added] [Tab 2]

When the first IOM report was conducted under the law, however, animal studies were omitted from the standard for determining an association. The report states:

“For its evaluation and categorization of the degree of association between each exposure and a human health effect, however, the committee only used evidence from human studies.”

Gulf War and Health Volume 1, p. 72 [Tab 3]

The authors of the report went on to say, and you will no doubt hear today, "But we did consider animal studies. We considered them for biological plausibility."

But under their methodology, "biological plausibility" does not even come into play unless there has been a previous finding of an association, based exclusively on human studies. [Tab 4] The salient fact is that they did not consider animal studies in determining whether an association exists between an exposure and an illness, as required by law, and the only question that matters in the determination of benefits.

To express conclusions as to whether an association exists, the authors set up five "Categories of Association." [Tab 4] Each substance was ranked according to these categories.

The authors of the report offered the following explanation of where the categories came from:

"The categories closely resemble those used by several IOM committees that evaluated . . . herbicides used in Vietnam [and other substances]...because they have gained wide acceptance for more than a decade by Congress, government agencies, researchers, and veteran groups." Gulf War and Health, Volume 1, p. 83 [Tab 5]

It is revealing to compare a category of association used in the Vietnam studies with the same category used in the first Gulf War report (and all subsequent reports).

Vietnam:

“Sufficient Evidence of an Association. Evidence is sufficient to conclude that there is a positive association. That is, a positive association has been observed between herbicides and the outcome in studies in which chance, bias, and confounding could be ruled out ...”

Vietnam and Agent Orange: 1996 Update [emphasis added] [Tab 6]

Gulf War:

“Sufficient Evidence of an Association. Evidence is sufficient to conclude that there is a positive association. That is, a positive association has been observed between an exposure to a specific agent and a health outcome in human studies in which chance, bias, and confounding could be ruled out ...”

Gulf War and Health: Volume I, p. 83 [emphasis added] [Tab 6]

The Gulf War category does indeed “closely resemble” the Vietnam category. It tracks it almost precisely . . . with the exception of a single word. The word “human” has been inserted in the Gulf War category.

Like the earlier smokescreen regarding biological plausibility, this change was no accident. It was a deliberate act to subvert the intent of Congress. And it has been

successful to this moment. It has been the straightjacket into which every IOM committee has been put when asked to review Gulf War research.

This straightjacket has immense consequences, because animal studies are the major source of new scientific knowledge on these substances. The report of the Research Advisory Committee issued last year lists sixteen studies on low-level exposures to sarin, and twenty-eight studies on combinations of exposures – most of them done in the last few years, and all of them done in animals. [Tab 7]

The law also said that the IOM was to consider combinations of exposures, and they haven't. The law said they were supposed to consider undiagnosed illnesses, and they haven't. [Tab 1, Tab 13]

The most egregious example of this distortion involved recent animal studies on the nerve gas sarin, which showed that, contrary to previous belief, low level exposures, below the level required to produce symptoms at the time of exposure, could produce long-term effects on the nervous and immune systems. Then-VA Secretary Principi wrote the Institute of Medicine: "Recently a number of new studies have been published on the effects of sarin on laboratory animals." He asked the IOM to report back on whether the research affected earlier IOM conclusions regarding the "long-term health consequences of exposure to low levels of sarin." Gulf War Review, Vol. 11, No. 2, March 2003, p. 4 [Tab 8]

Last year, the IOM delivered its report. The report did not consider animal studies in the all-important categories of association, even though new animal studies were the only reason for doing the report. Not surprisingly, it found no evidence of association.

[Tab 9]

This year, the VA initiated three new IOM Gulf War reports, which are underway at this moment. They were not reviewed by the Research Advisory Committee, as required by the 1998 statute. One purports to be a broad review of Gulf War illnesses literature: "An IOM Committee will review, evaluate, and summarize the peer-reviewed scientific and medical literature to determine what this information taken together can tell us about the health status of Gulf War veterans." [Tab 10]

Again, however, the study design excludes animal studies.

It also excludes government Gulf War reports, such as the comprehensive 2003 Department of Defense Final Report on Pesticides, which concluded that "[i]t is likely that at least 41,000 servicemembers may have been overexposed to pesticides" and that "[o]verexposures to pesticides, particularly organophosphates and carbamates, may have contributed to the unexplained illnesses reported by some Gulf War veterans." [Tab 11]

These distorted IOM reports are being used widely by the Department of Veterans Affairs, not just for benefits determinations. On September 15, VA Undersecretary of Health, Dr. Jonathan Perlin, sent an information letter to VA doctors who treat Gulf

veterans who may have been exposed to low levels of sarin. He assured them that “[a] 2000 congressionally-mandated review and a 2004 update conducted by the IOM concluded, based upon their review of a large body of scientific literature . . . , that the evidence did not support any long-term health effects following sub-clinical sarin exposure.” [Tab 12]

In summary, this fraud has gone on since 1998 and continues to go on. It has defied the will of Congress. It has distorted the workings of the Institute of Medicine. It has denied the Secretary of Veterans Affairs accurate information on which to determine benefits due ill veterans. It has misled veterans and their doctors.

Most tragically, it has misdirected researchers down blind alleys and away from paths that might have led to treatments for these debilitating illnesses.

Mr. Chairman, the Gulf War was the major military conflict of the United States in the last quarter of the twentieth century. Six hundred and ninety seven thousand Americans served. According to the Department of Veterans Affairs own most recent study, twenty-five percent of them are ill with chronic multisymptom illnesses. That means that more Gulf veterans are ill than all the American troops in Iraq today.

But no one ever hears about it. No one knows about it. No one does anything about it. Why? Because of this. Because of the people who did this, and who are perpetuating it today, who undermine the Secretary’s research commitments.

I ask myself: what kind of country are we living in where we send men and women to war, and government officials treat them like this when they return?

Mr. Chairman, I urge Congress to use every power at its command to investigate this matter and ensure that the persons responsible are removed from positions of authority and punished. Until they are, there will be no meaningful progress on Gulf War illnesses research to improve the lives of ill veterans.

The IOM failed to follow the 1998 law in other material respects. The law directed the IOM to identify and consider the illnesses that have occurred in Gulf veterans “including diagnosed illnesses and undiagnosed illnesses.” 38 USC Sec. 1117, note Sec.

1603(c)(1)(B) [Tab 1]

The IOM reports have never addressed undiagnosed illnesses. These are the constellation of symptoms commonly referred to as “Gulf War illnesses” or “Gulf War Syndrome” that are the central reason why this legislation exists and which affect at least 25 percent of those who served in the Gulf War, as shown by multiple studies. The second IOM Gulf War report acknowledged that the Committee was not charged with addressing “nonspecific illnesses that lack defined diagnoses . . .,” contradicting the law. Gulf War and Health Volume 2, p. 13. [Tab 13]

The law also defines toxic agents to include combinations of exposures (“whether through exposure singularly or in combination.”) 38 USC Sec. 1117, note Sec. 1605(1) [Tab A] The second IOM report also acknowledged that “exposure to multiple agents” was not within the Committee’s charge. Gulf War and Health Volume 2, p. 13 [Tab 13]

The law provides the following standard for the Secretary to use in determining whether a positive association exists, and thus whether a presumption of service connection is warranted:

“An association between the occurrence of an illness in humans or animals and exposure to an agent, hazard, or medicine or vaccine shall be considered to be positive . . . if the credible evidence for the association is equal to or outweighs the credible evidence against the association.” 38 USC Sec. 1118(b)(3) [Tab 2]

The IOM “categories of association” place a substantially higher level of proof than the statute requires.

“Sufficient Evidence of an Association. Evidence is sufficient to conclude that there is a positive association. That is, a positive association has been observed between an exposure to a specific agent and a health outcome in human studies in which chance, bias, and confounding could be ruled out . . .”

Gulf War and Health: Volume I [Tab 6]

In summary, VA and the IOM have repeatedly and deliberately disregarded explicit statutory direction in implementing the law.

I urge Congress to direct VA to enter into a new contract with the Institute of Medicine to prepare new reports on the association between the substances to which veterans were exposed and diagnosed and undiagnosed illnesses, in accordance with the statute in all respects. Alternatively, I recommend that Congress direct VA to enter into a contract with an alternate not-for-profit scientific organization that is not a part of the government and has "expertise and objectivity comparable to that of the National Academy of Sciences," as contemplated by the statute in the event that an acceptable agreement could not be reached with the National Academy of Sciences. 38 USC Sec. 1117, note Sec. 1603(k)(1) [Tab 1]

Finally, I recommend that Congress designate that VA funding for Gulf War illnesses research should go to a qualified nonfederal institution to develop and manage the research portfolio, both through research conducted in-house and through external research by VA and non-VA researchers selected on the basis of contracts and/or competition. An example of such an institution is the Boston University Center for Interdisciplinary Research in Environmental Exposures and Health. It is apparent that there is a conflict of interest for VA to manage research in an area where major benefits determinations are also at stake.